

Message Text

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E.O. 11652: N/A

TAGS: BEXP JA

SUB: TRADE FACILITATION COMMITTEE: CASE NO. 4 --
ABBOTT LABORATORIES

REF: TOKYO 04018

1. SUMMARY: COMMERCE FORWARDING NEW INFORMATION ON ABBOTT LABORATORIES CASE THAT REBUTS GOJ RESPONSE TO THEIR COMPLAINT. EMBASSY REQUESTED TO REOPEN THIS CASE IN TFC, END SUMMARY.

2. COMMERCE (USDOC) HAS RECEIVED A LETTER FROM ABBOTT LABS (COPY BEING SENT TO EMBASSY) SUPPLYING ADDITIONAL FACTS TO REBUT GOJ'S RESPONSE TO THEIR COMPLAINT (REFTEL). IN LIGHT OF NEW EVIDENCE PRESENTED, USDOC BELIEVES CASE SHOULD BE LIMITED OFFICIAL USE

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REOPENED.

3. REQUEST EMBASSY PRESENT CASE TO TFC OFFICIALS AND MHW
ALONG FOLLOWING LINES: BEGIN TEXT:

A. SUMMARY OF CASE:

US IS SUBMITTING TFC CASE NO. 4 FOR RECONSIDERATION IN LIGHT OF NEW INFORMATION PROVIDED BY ABBOTT LABS ON EFFECTIVENESS OF ITS HEPATITIS TEST AUSRIA. WE BELIEVE THAT THE NEW INFORMATION RESPONDS TO THE MAIN POINTS MADE IN GOJ'S MARCH 7 LETTER ON THIS CASE AND REQUEST RELIEF AS NOTED BELOW.

B. FACTS:

ABBOTT LABS, THROUGH ITS JOINT-VENTURE SUBSIDIARY DAINABOT, HAS ATTEMPTED TO GAIN MINISTRY OF HEALTH AND WELFARE (MHW) APPROVAL FOR THE USE OF ITS 3RD GENERATION HEPATITIS TEST AUSRIA SINCE ITS APPROVAL BY THE USG IN 1972.

IN ITS MARCH 7 RESPONSE, GOJ STATED:

(1) MHW HAS NOT APPROVED ANY REAGENTS, INCLUDING AUSRIA, FOR DETECTING HBS ANTIGEN UNDER THE PHARMACEUTICAL AFFAIRS LAW (PAL) AND THAT APPROXIMATELY ONE YEAR WILL BE REQUIRED TO GRANT OR REFUSE APPROVAL GIVEN (I) THE NEED FOR CAREFUL STUDY, TESTING AND ANALYSIS; AND (II) THE "DOUBTFUL EFFECTIVENESS" OF HEPATITIS TESTS SUCH AS AUSRIA IN DETECTING A PECULIAR AND DOMINANT JAPANESE SUB-TYPE "ADR" OF HBS ANTIGEN; AND

(2) THE JAPAN RED CROSS WAS GIVEN "ADMINISTRATIVE GUIDANCE" LIMITED OFFICIAL USE

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BY MHW TO USE A REVERSE PASSIVE HEMAGGLUTINATION TEST (R-PHA) BEGINNING IN APRIL 1976.

THE INFORMATION SUPPLIED TO USG BY ABBOTT LABS PERTAINS TO APPROVAL UNDER PAL AND SEPARATELY FOR THE JAPAN RED CROSS:

(1) MHW HAS PERMITTED THE SALE OF AUSRIA AS A CHARGED CLINICAL UNDER A "GRANDFATHER CLAUSE" TO THE PAL; HAS GIVEN UNOFFICIAL RECOGNITION TO ITS VALUE AND SAFETY BY ALLOWING IT TO BE USED IN ABOUT 25 PERCENT OF ALL HEPATITIS TESTS PERFORMED IN JAPAN; AND HAS HAD AMPLE TIME TO EVALUATE AND TEST AUSRIA SINCE ITS FIRST USE IN JAPAN IN 1972. THE FIRST FORMAL LICENSE APPLICATION FOR ITS APPROVAL UNDER PAL BEING MADE IN 1974, AND A REVISED LICENSE APPLICATION IN MAY 1976. FURTHERMORE, MHW ALREADY POSSESSES DATA ESTABLISHING THAT AUSRIA IS MOST EFFECTIVE IN DETECTING THE JAPANESE SUB-TYPE "ADR." DAINABOT HAS SUPPLIED MHW WITH OVER 3000 CASES INVOLVING DIFFERENT JAPANESE HOSPITALS WHICH SHOWED AUSRIA DETECTED 1.5 TO 10 TIMES AS MANY POSITIVES AS DID OTHER HEPATITIS TESTS. PAL APPROVAL IS SOUGHT BY ABBOTT SINCE IT WOULD PERMIT HOSPITALS TO GAIN REIM-

BURSEMENT FOR USE OF AUSRIA UNDER THE NATIONAL HEALTH INSURANCE PLAN; THUS EXPANDING SALES OF AUSRIA IN JAPAN.

(2) THE TEST PRESENTLY USED BY THE JAPAN RED CROSS UNDER

MHW "ADMINISTRATIVE GUIDANCE" IS A LESS SENSITIVE AND OBJECTIVE SUBSTITUTE FOR AUSRIA; A REQUEST BY THE JAPAN RED CROSS TO MHW TO PURCHASE AUSRIA IN 1976, FOLLOWING EXTENSIVE TESTING, WAS REJECTED BY MHW; AND A DECISION BY MHW TO ALLOW THE JAPAN RED CROSS TO USE AUSRIA, JUST AS PRIVATE HOSPITALS AND DIAGNOSTIC CLINICS NOW USE IT, COULD BE MADE WITHOUT FORMAL APPROVAL UNDER PAL.

C. ARGUMENT:
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THE EFFECTIVENESS OF AUSRIA IN DETECTING HBS ANTIGENS HAS BEEN DEMONSTRATED BOTH IN TESTS AND IN ACTUAL USE. THE FACT THAT AUSRIA IS PRESENTLY USED IN ABOUT ONE-QUARTER OF ALL HEPATITIS TESTS IN JAPAN TESTIFIES TO ITS SAFETY AND VALUE. MOREOVER, UNDER A GRANDFATHER CLAUSE TO THE PAL, MHW HAS ALLOWED THE SALE AND USE OF AUSTRIA AS A CHARGED CLINICAL IN PRIVATE HOSPITALS AND DIAGNOSTIC CLINICS.

WITH RESPECT TO THE GOJ RESPONSE THAT AUSRIA IS NOT EFFECTIVE IN DETECTING THE JAPANESE SUB-TYPE "ADR," DAINABOT HAS SUPPLIED MHW WITH TEST RESULTS OF OVER 3000 CASES FROM DIFFERENT JAPANESE HOSPITALS SHOWING THAT AUSRIA DETECTED 1.5 TO 10 TIMES AS MANY POSITIVES AS THE OTHER TESTS. IN ADDITION, THE JAPAN RED CROSS HAS ALREADY REQUESTED PERMISSION TO PURCHASE AUSRIA BUT BEEN REFUSED, AND THE TEST IT USES, UNDER MHW "ADMINISTRATIVE GUIDANCE," IS A LESS SENSITIVE SUBSTITUTE FOR AUSRIA.

FINALLY, EVEN IF AUSRIA WAS NOT IN CURRENT USE, AND ITS EFFECTIVENESS NOT FULLY SHOWN, MHW HAS HAD MORE THAN ADEQUATE TIME TO EVALUATE AND TEST AUSRIA -- IT HAS BEEN SIX YEARS SINCE IT WAS FIRST INTRODUCED INTO JAPAN AND FOUR YEARS SINCE ABBOTT LABS FIRST APPLIED FOR A FORMAL LICENSE.

THEREFORE, GIVEN ITS PROVEN EFFECTIVENESS GENERALLY, AND IN PARTICULAR, IN DETECTING THE JAPANESE SUB-TYPE OF HEPATITIS FORMAL APPROVAL SHOULD BE OBTAINABLE UNDER PAL IN LESS THAN A FULL YEAR. PENDING FORMAL APPROVAL, MHW SHOULD EXPEDITIOUSLY AUTHORIZE THE JAPAN RED CROSS TO PURCHASE AND USE AUSRIA.

D. RELIEF SOUGHT:
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1) MHW APPROVAL UNDER PAL SHOULD BE GIVEN TO AUSRIA SO AS TO ALLOW REIMBURSEMENT UNDER THE NATIONLA HEALTH INSURANCE PROGRAM.

2) PENDING SUCH APPROVAL MHW SHOULD AUTHORIZE THE JAPAN RED CROSS TO PURCHASE AND USE AUSRIA.

4. EMBASSY MAY USE FOLLOWING TALKING POINTS IN DISCUSSIONS OF CASE WITH MHW AND JAPANESE TFC OFFICIALS: (1) AUSRIA LICENSE APPLICATIONS IN 1974 AND MAY 1976 INCLUDED DETAILED CLINICAL DATA CONCERNING THE SAFETY AND EFFECTIVENESS OF AUSRIA, INCLUDING: TEST RESULTS, EXPLANATION OF METHODS OF PRODUCTION, PROCEDURES AND METHODS OF CONTROL, THE USE OF REFERENCE PANELS, EXPLANATIONS ON DIFFERENT SUBTYPES, ETC. WAS THIS DATA EVALUATED BY MHW AT THE TIME OF LICENSE APPLICATIONS? IF SO, WHY IS IT NECESSARY FOR THE "EXPERT GROUP" TO TAKE A YEAR TO REACH ITS CONCLUSIONS? (2) IN ADDITION TO THE DATA SUPPLIED TO MHW BY DAINABOT CONCERNING AUSRIA'S EFFECTIVENESS, THE RED CROSS, UNDER THE ADMINISTRATIVE SUPERVISION OF MHW, HAS DONE EXTENSIVE TESTING ON AUSRIA AND FOUND IT TO BE BY FAR THE MOST EFFECTIVE DIAGNOSTIC TEST FOR HEPATITIS DETECTION AVAILABLE. IN LIGHT OF THE RED CROSS FINDINGS AND RECOMMENDATION THAT AUSRIA BE PURCHASED AND USED, HOW DOES MHW EXPLAIN ITS REFUSAL TO GRANT AUTHORIZATION FOR THIS PURPOSE? (3) VARIOUS INTERNATIONAL SYMPOSIA ON HEPATITIS AND METHODS OF DETECTION HAVE BEEN HELD, INCLUDING ONE SPONSORED BY THE JAPAN MEDICAL FOUNDATION (JAPAN -- NOVEMBER 1976) AND ONE SPONSORED BY THE WORLD HEALTH ORGANIZATION (WHO) (GENEVA -- OCTOBER 1974). THESE SYMPOSIA PRESENTED ADDITIONAL EVIDENCE AS TO THE EFFECTIVENESS AND RELIABILITY OF THIRD GENERATION HEPATITIS TESTS SUCH AS AUSRIA.

5. BEGIN FYI: ABBOTT HAS INFORMED US THAT MHW OFFICIALS ARE "FURIOUS" ABOUT THIS CASE AND MITI INTERVENTION IN LIMITED OFFICIAL USE

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THEIR DOMAIN. ABBOTT REPRESENTATIVES WERE WARNED, IN EFFECT, THAT THEY WOULD "WAIT A LONG TIME" THE NEXT TIME THEY NEEDED AN APPROVAL FROM MHW. MHW ATTITUDE LENDS ADDITIONAL IMPORTANCE TO FAVORABLE RESOLUTION OF THIS CASE AS TFC CREDIBILITY AND EFFECTIVENESS IS IN QUESTION.

6. OUR OBJECTIVES ARE EXPEDITIOUS APPROVAL OF AUSRIA UNDER

THE PAL (I.E., LESS THAN ONE YEAR), AND IMMEDIATE AUTHORIZATION FOR RED CROSS PURCHASE AND USE OF AUSRIA. HOWEVER, THE FOLLOWING COMPROMISE POSITION HAS BEEN AGREED TO BY ABBOTT: THE MHW COULD EVALUATE AUSRIA AT ITS OWN PACE, BUT WOULD AGREE TO EXPEDITIOUSLY AUTHORIZE AUSRIA FOR RED CROSS USE. END FYI.

7. ACTION REQUESTED: EMBASSY REQUESTED TO SUBMITT ABBOTT UPDATE TO JAPANESE TFC OFFICIALS AND DIRECTLY TO MHW ASAP. USDOC BELIEVES THAT IN VIEW OF EMBASSY'S RECENT COMMENTS ON FLEXIBLE APPROACH IN DETERMINING BEST CHANNELS TO RAISE A SPECIFIC CASE, DIRECT NEGOTIATIONS WITH MHW OFFICIALS WOULD BE THE BEST WAY TO BRING CASE TO A FAVORABLE RESOLUTION. VANCE

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